SUMMARY DECISION

DECISION SUPPORT

PATIENT EDUCATION/SELF MANAGEMENT

GOALS¹

• A1C Goal: <7-8% - personalize based on patient factors (See Attachment 1)

Blood Sugar: Fix the fasting first
 Then fix pre-prandial
 (goal glucose 80-130 mg/dl)
 Then fix post-prandial (goal glucose ≤ 180 mg/dl)

- Blood Pressure (BP) < 140/90 Lower target for some patients (See page 5)
- Statin treatment goal based on age and presence of known Atherosclerotic Cardiovascular Disease (ASCVD). (See page 6)

ALERTS

- ♦ BLOOD SUGAR < 70 mg/dl
- ♦ BLOOD SUGAR > 400 mg/dl
- **♦ ALTERED LEVEL OF CONSCIOUSNESS**

DIAGNOSTIC CRITERIA²

Test	Pre-Diabetes	Diabetes (DM)	Gestational Diabetes
A1C	5.7 - 6.4%	≥ 6.5%	-
Fasting Plasma Glucose*	100 - 125 mg/dl	≥ 126 mg/dl	≥ 92 mg/dl 1 hr ≥ 180 mg/dl 2 hr ≥ 153 mg/dl
Random Plasma Glucose	-	≥ 200 mg/dl	-

^{*}In the absence of unequivocal hyperglycemia, results should be confirmed by repeat testing. Only diagnostic in a patient with classic symptoms of hyperglycemia or hyperglycemic crisis.

INITIAL EVALUATION

History	 Complete clinical history including Cardiovascular Factors and 10 year CV risk calculation (See page End organ sequelae: Retinopathy, nephropathy, ne ASCVD, Peripheral Vascular Disease (PVD), Cerebrovascular Disease 	Symptoms of hypoglycemia	
Physical Exam	Vitals: especially BP and Body Mass Index (BMI) Fundoscopic (Ensure screening done) Cardiovascular	 Peripheral vascular – pulses Foot exam – quick check for wound risk, comprehensive monofilament test annually (See Attachment 2, page 18) 	
Diagnostics	Baseline A1C Fasting lipid panel Spot urine Albumin to Creatinine ratio	Creatinine (Cr)TSH	

TREATMENT OPTIONS

Therapeutic	Lifestyle	Changes:	The bas			for	all
Medications	See Algor	rithms page	s 2-3		- ,		
Step 1: Metfo	ormin						
Step 2: Sulfo	nylurea, P	ioglitazone	, Basal In	sulin			
(Patie	ents with kr	nown ASCVI	See pag	e 6)			
Step 3: Basa	l Insulin, if	not already	on, then	add:			
i. 1 d	dose regula	ır insulin witl	n largest n	neal, o	r other (See	page	3)
ii. 2 (doses of re	gular insulin	with meal	S			
iii. Ac	ljust insulin	based on pe	ost-prandi	al bloc	d sugars		
Step 4: Cons	ider altern	ative medic	ation cla	sses (GLP-1, SGL	Γ2, oι	r
DPP-	4 if all nonf	ormulary red	quirements	are m	net		
Marria							

MONITORING

- PCP/Care Team visits as clinically appropriate
- A1C at goal: at least every 180 days, or as clinically appropriate
- A1C NOT at goal: at least every 90 days more frequently if actively titrating meds (See page 7)
- Watch for risk of Clinical Inertia: Set goals, actively titrate until at goal

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Information contained in the Care Guide is not a substitute for a health care professional's clinical judgment. Evaluation and treatment should be tailored to the individual patient and the clinical circumstances. Furthermore, using this information will not guarantee a specific outcome for each patient. Refer to "Disclaimer Regarding Care Guides" for further clarification.

https://cchcs.ca.gov/clinical-resources/

2018 ADA Standards of Care, Diabetes Care, Vol 41, Supplement 1, January 2018.

²Adapted from ADA Standards of Medical Care in Diabetes 2018, Abridged for Primary Care Providers, Page 2, Table 1, Criteria for the Screening and Diagnosis of Diabetes

DECISION SUPPORT PATIENT EDUCATION/SELF MANAGEMENT **SUMMARY** PHARMACOLOGIC THERAPY IN TYPE 2 DM: 2018 ADA AND CCHCS RECOMMENDATIONS¹ -If A1C < 9 %, start here STEP 1 **Monotherapy** Metformin Start 500 mg qd. Check FSBS. If not controlled, titrate q 3-7 days to max dose of 2500 mg qd. Monitor B12 level periodically. STEP 2 -If A1C ≥ 9 %, start here **Dual Therapy** Metformin Metformin Metformin 2 A. If NO ASCVD* **Basal Insulin Pioglitazone** Sulfonylurea** or or (TZD) Long-acting or Metformin Metformin Metformin Metformin 2 B. With Known Empagliflozin **Pioglitazone** ASCVD* Basal Insulin (SGLT2) or Sulfonylurea** or or or (TZD) Long-acting Liraglutide $(GLP-1)^{\dagger}$ With Endocrinologist Recommendation (see page 4) -If A1C ≥ 10 %, start here STEP 3 If the patient has met all nonformulary **Triple Therapy** requirements: Metformin Metformin Metformin 1. Has failed to reach goals with adequate trial of oral Insulin (basal or **Pioglitazone** meds, and at least 3 Sulfonylurea** month trial of basal insulin, 70/30 BID) (TZD) and 1 dose daily of + prandial insulin, GLP-1 or 2. Has had consult with Insulin Registered Dietitian, SGLT2 or Start with basal, Lantus or Insulin 3. Is engaging in lifestyle or DPP-4⁺ or NPH, and add Prandial insulin (see page 3) changes, and With then adjust based on 4. Has seen an Endocrinologist endocrinologist who post-prandial blood sugar as Recommendation recommends the preferred needed (see page 3) (see page 4) nonformulary meds.

BOLD = formulary medications

^{*}ASCVD defined as coronary artery disease, cerebrovascular disease, or peripheral arterial disease of atherosclerotic origin. Screening for CAD in asymptomatic patients is not recommended.

^{**}Taper and stop sulfonylurea when starting insulin other than basal insulin.

¹Adapted from ADA 2018, Diabetes Care Volume 41, Supplement 1, Figure 8.1, January 2018.

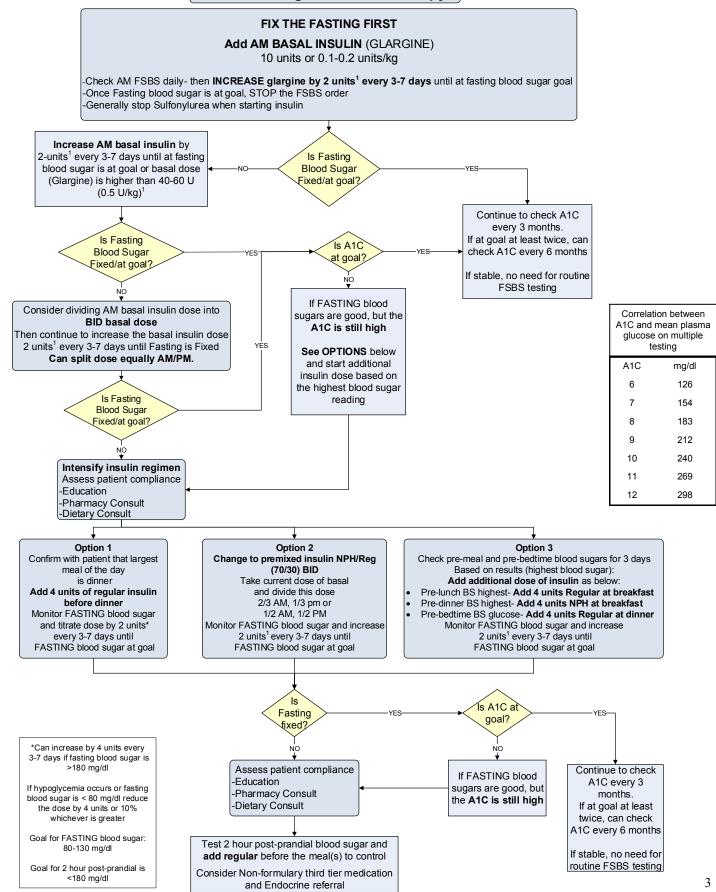
SUMMARY

DECISION SUPPORT

PATIENT EDUCATION/SELF MANAGEMENT

INSULIN ALGORITHM¹

If A1c not at goal on Dual Therapy



SUMMARY

DECISION SUPPORT

PATIENT EDUCATION/SELF MANAGEMENT

TREATMENT OPTIONS

SETTING GLYCEMIC GOAL WITH PATIENT: Generally <7%, but can be <6.5% or <8.0 based on patient factors (See Attachment 1, page 17)

II. EDUCATION AND THERAPEUTIC LIFESTYLE CHANGES:

Patient Self-Management

• All patients with DM should participate in DM self-management education/support to assist with implementing and sustaining skills and behaviors needed for ongoing self-management. [B]*

Nutrition

- Consider diet counseling (onsite or via telemedicine) to provide patients with practical tools for day-to-day meal choice selection and better food choices at canteen.
- ◆ Provide DM dietary patient handouts: From the Dietary page on Lifeline (http://lifeline/HealthCareOperations/ MedicalServices/Dietary/Pages/Home.aspx) → Under Quick Links on the right → Select Diabetic Education Handouts

Weight loss

- If BMI ≥ 25 in patients with pre-diabetes or DM, establish a realistic weight loss goal at the time of diagnosis.
- Weight loss of 2 8 kg may provide clinical benefits to those with Type 2 DM, especially early in the disease process.

Exercise

- Ensure patients on insulin or insulin secretagogues (sulfonylureas) understand the possibility of hypoglycemia with ↑ activity.
- The ADA recommends: at least 150 minutes of moderate/vigorous intensity exercise, spread out over ≥ 3 days/wk with no more than 2 consecutive days without activity. If younger and more physically fit: at least 75 minutes/week of vigorous intensity or interval training may be sufficient. [B]*

Psychosocial/Mental Health

- Ensure depression or other mental health issues are addressed, especially if the patient is non-adherent.
- Involve and engage the patient, promote self management skills, explore fears, and consider case coordination.

III. MEDICATIONS (See pages 14-16):

Start medications promptly when lifestyle efforts are not sufficient in achieving or maintaining glycemic goals.

Titrate every 3-7 days until fasting blood sugar goal is reached then monitor A1C and adjust if not maintaining glycemic control goal.

Medication choice – see algorithm (Pharmacologic Therapy in Type 2 DM page 2).

- Step 1: Metformin
- Step 2: Add Sulfonylurea (Glipizide NOT Glyburide), or TZD (Pioglitazone), or Basal Insulin, (or if ASCVD, see page 2).
- Step 3: Add Basal Insulin (if not already on) glargine (QD or BID), or NPH (BID), or 70/30 BID, if still not in control add:
 - -Prandial insulin at largest meal. If still not in control, add
 - -Prandial insulin at multiple meals. If still not in control, monitor
 - -Post-prandial glucose level and adjust prandial insulin
- Step 4: Fourth-line DM medications GLP-1 (Liraglutide) or SGLT2 (Empagaflozin or Canagliflozin) have some data suggesting lower cardiovascular mortality, may be considered in patients with established CV disease with endocrinologist referral (see below).

Nonformulary forth-line Diabetes Medications may be considered in patients with established CV disease:

Before prescribing the CCHCS preferred nonformulary medication (see below) ensure all of the following:

- 1. The patient has failed to reach goal with an adequate trial of maximally tolerated doses of oral medications, and at least three month trial of basal insulin and 1 dose daily of prandial insulin.
- 2. The patient has had consult with a Registered Dietitian.
- 3. The patient is engaging in lifestyle changes.
- 4. The patient has seen an endocrinologist who recommends one of the below classes/medications:
 - -GLP-1(Liraglutide),
 - -SGLT2 (Empagaflozin), or
 - -DPP-4 (Sitagliptin) (limited efficacy)

Note: These medication classes have limited long-term safety data and are nonformulary.

*[X] letter grade represents strength of recommendation from 2018 ADA Evidence–Grading System – See Attachment 4, page 20.

SUMMARY DECISION SUPPORT PATIENT EDUCATION/SELF MANAGEMENT

CLINICAL INERTIA

Clinical Inertia: The failure of health care providers to initiate or intensify therapy when indicated is a big problem in the management of diabetes and diabetes related co-morbidities such as hypertension.

Physician/Provider-, patient-, and health care-system-related factors all contribute.

Physician/Provider factors:

- Failure to set clear goals
- Failure to initiate treatment
- Failure to titrate treatment to achieve goals
- Failure to identify and manage comorbidities (i.e., depression)
- Reactive rather than proactive care

Clinical Consequences of Clinical Inertia:

Patient factors:

- Denial that disease is serious; absence of symptoms
- Low health literacy
- Too many medications/medication side effects
- Poor communication between the physician and the patient
- Lack of trust in physician
- Depression or substance abuse
- Delays in treatment intensification can negatively affect a patient's prognosis and contribute to patients living with suboptimal glycemic blood pressure or lipid control for years, leading to adverse outcomes and increased risk of complications.

Overcoming Clinical Inertia:

- Engage with the patient regarding the progressive nature of Type 2 DM, and encourage lifestyle modification behaviors from beginning of diagnosis, and throughout treatment.
- Ensure the patient understands the goals of their treatment, are involved in managing their disease, and trust their care team's medical recommendations.
- Use the Complete Care Model to engage entire team in managing/monitoring the patient's Type 2 DM including BP and lipids.
- Have a care team member see the patient frequently when not at goal and titrate medication aggressively.

HYPERTENSION MANAGEMENT IN PATIENTS WITH DIABETES - 2018 ADA RECOMMENDATIONS

RECOMMENDED BLOOD PRESSURE (BP) GOALS

- High risk factors for CVD include: hypertension, dyslipidemia, smoking, family history, chronic kidney disease (CKD), albuminuria and DM.
- Significant controversy still exists in the literature regarding the target HTN treatment goals. Below are the recommendations by ADA, ACC/AHA and JNC.

Recommendation for DM	BP Goal	
ADA (2018) Most patients with DM	< 140/90	
Individuals at high risk of CVD	< 130/80	
JNC 8 (2014)	< 140/90	
ACC/AHA (2017)	< 130/80	

TREATMENT RECOMMENDATIONS

Blood Pressure*	Treatment Modalities	Evidence	Anti-Hypertensive Medications for Type 2 DM
> 120/80	Lifestyle Changes (↓ Wt, Na, ETOH, ↑K+)	[B]	All four of these four first line agents are useful and effective [A] ACC/AHA Executive Summary ¹
≥ 140/90	Med + Lifestyle Changes Prompt initiation Timely subsequent titration	[A]	-ACEI or ARB if albuminuria present -Calcium channel Blockers -Thiazide-like diuretic
≥ 160/100	2 Med + Lifestyle Changes Prompt initiation Timely subsequent titration	[A]	-DO NOT USE ACEI AND ARB SIMULTANEOUSLY. Do not use ACEI/ARB with direct renin inhibitors (currently only Aliskiren®) [A]

^{*}For diagnosis: only one blood pressure value has to be high, either systolic or diastolic blood pressure.

¹Whelton, chairman, 2017 ACC/AHA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: Executive Summary" Journal of the American College of Cardiology, 2017.11.005.

SUMMARY DECISION SUPPORT PATIENT EDUCATION/SELF MANAGEMENT

LIPID MANAGEMENT IN PATIENTS WITH DIABETES

LDL GOAL FOR PATIENTS WITH DIABETES WITH AND WITHOUT ASCVD

	No LDL treatment goal Monitoring LDL/lipid panel done to confirm adherence
Overt ASCVD – includes those with CVD, cerebrovascular disease, and peripheral vascular disease	Treatment goal LDL < 70 mg/dL or at least 50% reduction

LIPIDS- STATIN TREATMENT FOR PATIENTS WITH DIABETES¹ (For details see CCHCS Lipid Care Guide)

STATINS for DM

• Statin treatment initiation and monitoring is <u>based on age and risk factors and ASCVD status</u> (see below).

AGE	RISK FACTORS PRESENCE OF ASCVD	RECOMMENDED STATIN DOSE INTENSITY*	MONITORING AND TREATMENT GOALS FOR ASCVD
< 40 years	None	None	At initiation of therapy, 4-12 weeks after a change, and
	CVD risk factors**	Moderate	annually, or more frequently as clinically indicated (monitoring is primarily done to confirm adherence)
	Overt ASCVD***	High [A]	Lipid panel as indicated to achieve target LDL < 70 mg/dL (2018 ADA, 2013 AHA/ACC) 2017 ACCE recommends goal of <55 mg/dL
≥ 40 years	None	Moderate [A]- patients 40-74 yrs [B]- patients ≥ 75 yrs	At initiation of therapy, 4-12 weeks after a change, and annually, or more frequently as clinically indicated
		High [A]- patients 40-74 yrs [B]- patients ≥ 75 yrs	(monitoring is primarily done to confirm adherence)
	Overt ASCVD***	High [A]- all patients > 40 yrs	Lipid panel as indicated to achieve target LDL < 70 mg/dL (2018 ADA, 2013 AHA/ACC) 2017 ACCE recommends goal of <55 mg/dL

High-intensity statin—Atorvastatin 40 - 80 mg/d

Moderate-intensity statin—Atorvastatin 10 - 20 mg/d or Simvastatin 20-40 mg/d

HYPERTRIGLYCERIDEMIA on Statin: Combination Therapy

- For patients with fasting triglyceride levels ≥ 500 mg/dL, evaluate for secondary causes of hypertriglyceridemia and consider medical therapy to reduce the risk of pancreatitis. **[C]**
- Statin/fibrate combination has not been shown to improve atherosclerotic cardiovascular disease outcomes and is generally not recommended. [A]
- However, therapy with statin and fenofibrate may be considered for men with:
 - -Triglyceride level ≥ 204 mg/dL (2.3 mmol/L) AND
 - -High-density lipoprotein (HDL) cholesterol level < 34 mg/dL (0.9 mmol/L) [B]

^{*}In addition to lifestyle therapy.

^{**}CVD risk factors include LDL cholesterol ≥ 100 mg/dL, high blood pressure, smoking, albuminuria, CKD, and overweight and obesity.

^{***}Overt CVD includes those with cardiovascular disease, cerebrovascular disease, and peripheral vascular disease.

SUMMARY	DECISION SUPPORT PATIENT EDUCATION/SELF MANAGEMENT				
	MONITORING - ADAPTED FROM 2018 ADA RECOMMENDATIONS				
EXAMS					
Blood pressure	 Check vitals (In Cerner under "Results Review/vitals") for average BP since last visit If not at goal – Test between visits as clinically indicated while titrating medication At goal – Check each visit 				
Comprehensive foot exam and pulses	 Annually – All patients Document in Health Maintenance (Can add a reminder of when next exam is due) See page 10 for details on Diabetic Foot Care Monofilament exam by care team member (See Attachment 2, page 18) 				
Dental exam	Annually – Upon patient request				
LABS					
A1C	 Not at goal – Check every 90 days (minimum) At goal – Can be every 180 days (minimum) if stable over several months 				
Lipid panel	 At initial visit and if not on medication/statin: check every 5 years (or more often if indicated) If started on lipid medication, check baseline then: 4 – 12 weeks after initiation or change in dose. Annually or more frequently as clinically indicated (monitoring while on a statin is primarily done to confirm adherence unless known ASCVD) Patients with known ASCVD monitoring at least annually for goal of LDL < 70 mg/dL is recommended (2018 ADA) 				
B12* (For patients on Metformin)	 If hemoglobin, hematocrit, red cell indices suggestive or symptoms suggestive of anemia, neuropathy, or deteriorating renal function Consider annual level, as anemia is poor indicator of B12 deficiency 				
Urine microalbumin	 Annually – All patients (Spot urinary albumin to creatinine ratio) Cerner order – "Microalbumin, Random Urine with Creatinine" 				
Serum Creatinine and Glomerular Filtration Rate (GFR) estimate	 Annually in all patients with albuminuria See page 9 for GFR Estimation 				
Potassium	 Annually in all patients with albuminuria, on ACE inhibitors (ACEI), Angiotension II receptor blockers (ARBs), or diuretics 				
FSBS	 If ordered, check/document results at each visit – In Cerner under "Results Review/Vitals" Act on results, assess need for continued Fingerstick (FS) Do not order if not acting on results. (FS testing is very burdensome to patients & staff) May not be necessary for Type 2 diabetics who are diet treated or on only oral medications that are not associated with hypoglycemia Oral medication and basal insulin regimens: Once insulin dose stabilizes, may discontinue or monitor FS much less frequently especially if A1C is at goal Note: A fasting or pre-meal FS test is of little value if patient has eaten, defer test Consider a Keep-on-Person (KOP) glucometer if fasting or pre-meal tests are needed but difficult to obtain See Role of Sliding Scale Insulin on page 11 				

^{*}McCulloch, Metformin in the treatment of adults with type 2 diabetes mellitus, UptoDate Dec 2017; ADA 2018 "B12 as clinically indicated."

SUMMARY	DECISION SUPPORT P	ATIENT EDUCATION/SELF MANAGEMENT		
PREVENTIVE CARE				
VACCINES				
Influenza vaccine	Annually – Offer and encourage for all patients with DM			
 Age ≤ 65 years, one dose of PPSV23 is required Age > 65 years, one dose of PCV13 AND a one-time repeat PPSV23 is r Keep the PCV13 at least 1 year apart from the last PPSV23 after vaccina Keep the final PPSV23 dose at least 1 year from the PCV13 AND 5 years 		D a one-time repeat PPSV23 is required om the last PPSV23 after vaccination		
	PPSV23 (at 19-64 years) At least 1 year apart	PCV13 (at ≥ 65 years) At least 1 year apart PPSV23 (at ≥ 65 years) At least 5 years apart		
Hepatitis B (HBV) vaccine	 Recommended – 2017 CDC: Offer to all patients age 19-59 years and consider HBV vaccine in patients age > 59 years ACP Dec 2017: Vaccinate all unvaccinated adults at risk for infections due to sexual, percutaneous, blood, or mucosal exposure, chronic kidney disease, end stage renal disease, dialysis patients, or HIV infection, or travel to HBV-endemic regions 			
SCREENING				
Retinopathy screening	 Eye Exams: Can be performed by an optometrist Initial eye exam: indicated shortly afte Follow-Up eye exam: Annually 	er diagnosis in patients with Type 2 DM d well controlled DM – may consider every 2 years		
Cardiovascular Risk Calculator	- Gender - Diastolic - Race - DM - Total Cholesterol - Smoking - HDL	blood pressure blood pressure calc.com/cardiology/ASCVD/PooledCohort.aspx tanagement		
ASA for Primary Prevention	women > 60 who have at least on	ng ASCVD Risk calculator), including men > 50 years of age or e additional major risk factor for CVD other than DM (e.g., oking, albuminuria, family history of premature CVD)		

¹Centers for Disease Control Vaccines and Preventable Diseases: Pneumococcal Vaccination. Updated December 7, 2017. https://www.cdc.gov/vaccines/vpd/pneumo/index.html

SUMMARY DECISION SUPPORT PATIENT EDUCATION/SELF MANAGEMENT

DIABETIC NEPHROPATHY MONITORING

MICROALBUMINURIA - False Positives occur ensure 2 tests over 3 - 6 MONTHS)

- Measure urine albumin excretion <u>annually</u> starting at diagnosis.
- Order "Microalbumin, Random Urine with Creatinine."

 (Order includes microalbumin/creatinine ratio).
- Normal albuminuria: < 30 mg/day.
- Microalbuminuria: 30 to < 300 mg/day. Start treatment, reduces progression.
- Macroalbuminuria: ≥ 300 mg/day.

TREATMENT OF ALBUMINURIA		
DM with normal albumin and normal BP	No treatment indicated. Normotensive primary prevention is NOT recommended.	
DM with hypertension and normal albumin ACEI or ARB¹ (discontinue if serum Cr increases > 30% over baseline on initiation)		
DM with albuminuria (≥ 30 mg/ day) and normal BP	ACEI or ARB ¹ (discontinue if serum Cr increases > 30% over baseline on initiation)	

Treatments to reduce albuminuria should not reduce GFR. ACEI or ARB should be discontinued when serum creatinine concentration increases > 30% above the baseline value.**

GLOMERULAR FILTRATION RATE (GFR) ESTIMATION

- eGFR done *automatically* with Cerner order of: "Creatinine, Creatinine Clearance, BUN/Creatinine ratio, Basic Metabolic Panel or Comprehensive Metabolic Panel" (but NOT with Creatinine 24 hour urine).
- Complications of kidney disease correlate with **eGFR** (see table on Stages of CKD below).

STAGES OF CKD²

Stage	Description	GFR (ml/min/1.73m ²)
1	Kidney damage* with normal or increased GFR	≥ 90
2	Kidney damage* with normal or decreased GFR	60-89
3	Moderately decreased GFR	30-59
4	Severely decreased GFR	15-29
5	Kidney failure	< 15 or dialysis

^{*}Kidney damage is defined as abnormalities on pathological, urine, blood, or imaging tests.

MANAGEMENT OF	MANAGEMENT OF CKD IN DM ¹				
GFR (ml/min/1.73m ²)	Recommended Management				
All diabetic patients	Yearly measurement of creatinine, urinary albumin excretion, potassium				
45-60	Referral to a nephrologist recommended for CKD stage 3 or higher				
30-44	Monitor estimated GFR (eGFR) every 3 months				
	Monitor electrolytes, bicarbonate, calcium, phosphorus, parathyroid hormone, hemoglobin, albumin, weight every 3-6 months				
	Consider the need for adjustment of medication doses due to reduction in renal function				
< 30	Referral to a nephrologist				

¹National Kidney Foundation. KDOQI Clinical Practice Guideline for diabetes and CKD: 2012 update.

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^{**}Major side effects of angiotensin-converting enzyme inhibitors and angiotensin II receptor blockers. Normal M. Kaplan, M.D. et al. Up-to-Date July 10, 2014.

²Adapted from: Levey et al. National Kidney Foundation practice guidelines for chronic kidney disease; evaluation, classification, and stratification. Annuals Internal Medicine 2003; 139: 137-147.

SUMMARY DECISION SUPPORT PATIENT EDUCATION/SELF MANAGEMENT

DIABETIC FOOT CARE

HIGH RISK FEET

Risk for ulcers or amputations increased in patients with diabetes with any of the following:

- · Previous amputation
- Past foot ulcer/open ulcers
- Peripheral neuropathy/loss of protective sensation (LOPS)
- Foot deformity
- · Peripheral vascular disease

- Smoking
- · Poor glycemic control
- Visual impairment
- · Diabetic kidney disease, especially if on dialysis

Provide diabetic foot care education at least annually for all patients with High Risk Feet.

SUGGESTED FOOT EXAM ELEMENTS

History High risk feet conditions from above • Neuropathic symptoms: pain, numbness, tingling, prickling, pins and needles sensation • Vascular symptoms: claudication Impaired vision Tobacco use · Foot care practices, shoe wear Inspection • Skin: focal lesions e.g., calluses, maceration, ulcers, dry skin, tinea pedis • Nails: onychomycotic or dystrophic nails • Deformities: hammer toe, bunion, pes planus or pes cavus Peripheral arterial disease (PAD) suggested by absence of dorsalis pedis and posterior tibial pulses, Vascular dependent rubor, and capillary filling time of > 3 seconds **Exam** • Consider Ankle Brachial Index (ABI) in any patient with signs and symptoms of PAD, especially in diabetics > 50 years Test for LOPS using: Neurologic Sensory • 10-g monofilament test (See Attachment 2, page 18) Exam · And at least one of the following: ▶ Vibration using 128 Hz tuning fork tested at tip of great toe bilaterally ▶ Pinprick sensation, using a disposable pin applied just proximal to the toenail on dorsal surface of hallux using just enough pressure to deform skin. Inability to perceive pinprick over either hallux is an abnormal test result. ▶ Ankle reflexes

CONSULTATION, DIABETIC SHOES, AND ORTHOTICS

One or more abnormal results suggests LOPS

At least two normal tests (and no abnormal) rules out LOPS

- Consider consultation and/or authorization of diabetic shoes and/or orthotics for diabetic patients with high risk feet as defined above.
- Also consider consultation with Podiatry for patients with onychomycosis causing deformity of the nail or nail bed.
- Patients with diabetes and a diagnosis of diabetic sensory neuropathy with LOPS should be referred to podiatry for what might ordinarily be considered routine primary or personal care. The following procedures may pose a hazard when performed by a non-trained professional:
 - -Cutting or removing corns and calluses
 - -Trimming, cutting, clipping or debriding nails

SUMMARY

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PATIENT EDUCATION/SELF MANAGEMENT

SWITCHING BETWEEN NPH AND INSULIN GLARGINE

NPH to insulin glargine

- NPH once daily: Convert unit-for-unit (1:1) to glargine and give once daily.
- NPH twice daily: Glargine dose should be 80% of total NPH dose and given once daily.

Insulin glargine to NPH

• Convert unit-for-unit from glargine to NPH and give twice daily (e.g., 1/2 AM and 1/2 PM or 2/3 AM and 1/3 PM).

ROLE OF SLIDING SCALE INSULIN (SSI)

OUTPATIENT

National Guidelines - SSI:

- 2009: ADA DO NOT USE for outpatients and stop using long term SSI in DM.
- 2008: American Medical Directors Association recommends to AVOID.
- 2012: American Geriatrics Society - Beers Criteria Update Expert Panel recommends to AVOID.
- 2016: FBOP SSI NOT a recommended strategy for long-term management.

Reasons not to use SSI:

- Nonphysiologic Reactive to high blood sugar that already occurred and doesn't prevent elevation in future and leads to rollercoaster effect. (Nalysnyk, Glycaemic variability and complications in patients w DM, 2010)
- Requires patient to become hyperglycemic before treatment given as most SSI start at 180 mg/dL and provider alerts often > 300 mg/dL.
 (Konrad, Glycemic control in hospitalized patients not in ICU, beyond SSI, Am Family Physician 2010)
- · Greater patient discomfort.
- Increased nursing time due to increased monitoring.
- Increased nursing time due to increased number of injections administered.
- Typical notifications (e.g., < 60 and > 400 mg/dL) may result in periods of hypoglycemia or hyperglycemia without adjustments in therapy.
- SSI lends itself to a failure of adjustment: A large medical center retrospective study: 84% of SSI patients with hyperglycemia, only 18% had dose adjustments.

(Golightly, Management of DM in hospitalized patients, Pharmacotherapy 2006)

Appropriate use:

- Use <u>short term</u> SSI when titrating insulin, THEN STOP.
- May use temporarily when patient is acutely ill, or nothing by mouth for any reason.

INPATIENT

- 2010 American Family Physician Traditional SSI should be abandoned as the sole means of controlling blood sugar in hospitalized patients.
- 2016: ADA sole use of sliding scale insulin in the inpatient hospital setting is strongly discouraged.
- Patients treated with SSI alone had hyperglycemia
 300 mg/dL three times more often than other regimens.
 - (Queale, Glycemic control and SSI use in medical inpatients with DM, 1997)
- Basal insulin shown to provide superior glycemic control with less risk of hypoglycemia.

 (Maynard, improved inpatient use of basal insulin 2009)
- Recommended to use basal and basal/prandial insulin as the foundation.
 - Correction Factor insulin is ordered to be given prospectively with prandial insulin if needed and if used frequently, is added to the basal/prandial at previous meal.
- Limited use of SSI is occasionally needed on a temporary basis in extremely sick patients.

For FBOP Strategies to Replace SSI, go to the Provider Resource Library on Lifeline: http://lifeline/Pages/Home.aspx → Select Medical Services on the left → Select Provider Resource Library on the right → Under What's New → Select Diabetes CME Toolkit 2018 → Go to page 177 of 178.

SUMMARY

DECISION SUPPORT

PATIENT EDUCATION/SELF MANAGEMENT

ANTIHYPERGLYCEMIC MEDICATION CHARACTERISTICS

		ANTIHYP	ERGLYCE		MEDICATION CHA	ARACTERISTICS		
Medication Class		CV Effects		Cost	Advantages	Disadvantages	Additional Considerations	
mouroution	Miculculon Glass		CHF	0001	7 ta vantagoo	Diodavantagoo	radicional Contractations	
Metformin		Potential Benefit	Neutral	Low	•Extensive experience •Rare hypoglycemia •↓ CVD events (UKPDS**)	•Lactic acidosis risk (rare)	Gastrointestinal side effects common (diarrhea, nausea) Potential for B12 deficiency	
Sulfonylureas (2nd Generation) -Glipizide Do NOT use Glybu	ıride	Neutral	Neutral	Low	•Extensive experience •↓ Microvascular risk (UKPDS**)	•Hypoglycemia	•FDA Special Warning on increased risk of cardiovascular mortality based on studies of an older sulfonylurea (tolbutamide)	
A1C Reduction: 1	.0-2.0%*							
Thiazolidinedione "Glitazones" -Pioglitazone A1C Reduction: 0	98	Potential Benefit: pioglitazone	↑ Risk		•Rare hypoglycemia •Durability •↓ Triglycerides •↓ Risk of stroke and MI in patients without diabetes and with Insulin resistance and history of recent stroke or TIA	•Edema/heart failure •Bone fractures •↑ LDL-C (rosiglitazone)	•FDA Black Box: Congestive heart failure •Fluid retention (edema; heart failure) •Benefit in Nonalcoholic Fatty Liver Disease •Risk of bone fractures •Bladder cancer (pioglitazone)	
Insulin A1C Reduction: 1.5-3.5%*	Human Insulin	Neutral	Neutral	Low	•↓ Microvascular risk (UKPDS**)		 Injection site reactions Higher risk of hypoglycemia with human insulin (NPH or premixed formulations) vs. analogs 	
	Analogs			High		insulin) •Pulmonary toxicity (inhaled insulin)		
GLP-1 Receptor a "Glutides" -Liraglutide (prefe nonformulary) -Exenatide		Benefit: liraglutide+	Neutral		excursions •↓ Some cardiovascular	•↑ Heart rate •C-cell hyperplasia/ medullary thyroid tumors in animals •Injectable	•FDA Black Box: Risk of thyroid C-cell tumors (liraglutide, aliglutide, dulaglutide, exenatide, exenatide ER)	
-Exenatide ER -Aliglutide -Dulaglutide -Lixisenatide		Neutral: lixisenatide, exenatide ER				•Training requirements	excitation Ety	
A1C Reduction: 0	.5-1.0%*							
DPP-4 Inhibitors "Gliptins" -Sitagliptin -Saxagliptin -Linagliptin -Alogliptin		Neutral	Potential Risk: saxagliptin, aloglipton	High	•Well tolerated	•Angioedema/urticaria and other immune-mediated dermatological effects •↑ Heart failure hospitalizations	Potential risk of acute pancreatitis Joint pain	
A1C Reduction: 0	.5%-0.8%*							
SGLT2 Inhibitors "Flozins" -Canagliflozin -Empagliflozin (pi nonformulary) -Dapagliflozin	referred	Benefit: canagliflozin, empagliflozin+	Benefit: canagliflozin, empagliflozin	High	•↓ blood pressure	•Polyuria •Dizziness •↑ LDL-C •↑ Creatinine (transient)	•FDA Black Box: Risk of amputation (canagliflozin) •Risk of bone fractures (canagliflozin) •DKA risk (all agents, rare in T2DM) •Genitourinary infections	
A1C Reduction: 0	.5%-0.7%*						•Risk of volume depletion, hypotension •↑ LDL cholesterol	

⁺FDA approved for CVD benefit. CVD cardiovascular disease; DKA, diabetic ketoacidosis; DKD diabetic kidney disease; NASH, nonalcoholic steatohepatitis; RAs, receptor agonists; SQ subcutaneous; T2DM, type 2 diabetes.

CVD cardiovascular disease; DKA, diabetic ketoacidosis; DKD diabetic kidney disease; NASH, nonalcoholic steatohepatitis; RAs, receptor agonists; SQ subcutaneous; T2DM, type 2 diabetes.

Adapted from: Table 8.1– Drug specific and patient factors to consider when selecting antihyperglycemic treatment in adults with type 2 diabetes from ADA 2018, page S77 and Table 8.2—Pharmacology of available glucose-lowering agents in the U.S. for the treatment of type 2 diabetes from ADA 2018, page S79-S80.

*A1C Reduction values from McCulloch, Management of persistent hyperglycemia in type 2 diabetes mellitus. Options for Diabetes Table. Summary of glucose-lowering interventions. UptoDate. Mar 2018.

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SUMMARY

DECISION SUPPORT

PATIENT EDUCATION/SELF MANAGEMENT

MANAGEMENT OF HYPOGLYCEMIA IN CCHCS

PREVENTION

- Patients who are prone to hypoglycemia should have access to glucose tablets, glucose gel, or a diabetic snack.
- Staff members should also have ready access to glucose tablets or the equivalent.
- Patients receiving insulin or oral antihyperglycemic agents may develop hypoglycemia during illness, with greatly increased activity (exercise) level, or decreased food intake. Profound hypoglycemia may develop when meals are delayed or missed.
- Ask about hypoglycemic episodes at each visit.
- Custody staff shall ensure that patients receiving insulin have access to their next scheduled meal within 30 minutes of insulin injections.
- Elderly patients should be monitored for signs of hypoglycemia.
- · Patients must be counseled:
 - -Regarding the importance of a consistent diet and activity level.
 - -To report for insulin injection <u>prior</u> to eating (fasting) to ensure meaningful FS glucose results.
 - -To report for meals promptly after receiving insulin injections.
 - -To discuss with his/her provider possible insulin or oral hypoglycemic dosage adjustments during illness.
 - -To tell the RN if the FS is in fact, post prandial so it can be documented with the FSBS.

TREATMENT		
Classification of Hypoglycemia	Description	Treatment
Alert Value ≤ 70 mg/dL	Conscious with or without symptoms Requires treatment and adjustment of therapy	 15-20 grams of glucose preferred. But any form of carbohydrate that contains glucose can be used: Austin Peanut butter/cheese and crackers pack = 16 carbs and 3g of sugar. Keebler Graham cracker pack = 11 g carbs and 3g sugars. Clinic and KOP sugar tablets are 4 g of sugar each. There is also a 40% dextrose gel which have 22 grams of sugar each. Recheck in 15 minutes, if still <70 mg/dL, repeat above. Follow with high sugar content snack with low protein and fat*.
		Once normoglycemic (BS >80 mg/dl) – eat meal or snack.
		Consider bedtime snack if at continued risk.
Clinically Significant < 54 mg/dL	Serious and clinically important	Same as above with vigilance for progression to severe.
Severe Severe cognitive impairment or unconscious	Associated with immediate mortality and 5-year mortality and increases risk for development of dementia	(Crash carts carry a 1 mg syringe kit).
Requires third		Administer IV Dextrose as soon as it is available (Crash carts carry bags of Dextrose 50% solution)
party assistance		Prolonged monitoring may be required if on long-acting insulin or insulin secretagogues.
		If unexplained or recurrent severe, on long acting insulin or on insulin with poor oral intake: Admission to a medical unit for observation and stabilization may be indicated.
		ADA advises to increase glycemic targets for at least several weeks as it has been demonstrated to improve counter-regulation and hypoglycemic awareness.

^{*}Fat may retard and then prolong the acute glycemic response. In type II DM, protein may increase insulin response without increasing plasma glucose concentrations.

Adapted from 2018 ADA Vol 41, Supplement 1, Glycemic Targets, pg S61.

SUMMARY	DECISION SUPPORT	PATIENT EDUCATION/S	SELF MANAGEMENT	
ORAL DM MEDICATIONS				
DRUG CLASS / MEDICATION	Dosing	Adverse Effects / Interactions*	COMMENTS	
		BIGUANIDES		
Metformin (Glucophage [®]) Tablet (IR): 500 mg, 850 mg, 1000 mg tabs	Initial dose: 500 mg twice daily or 850 mg once daily with meals Titration: After 5-7 days if no GI side effects, increase dose by 500 mg weekly or 850 mg twice daily every other week. (Titrate dose slowly to minimize GI effects) Max dose: Max effective dose may be 1000 mg twice daily, often max effect seen at 850 mg twice daily. Modestly greater efficacy seen with doses up to 2500 mg/day (Doses > 2000 mg/day better tolerated if given three times daily with meals) Hepatic impairment: Avoid Renal impairment: Contraindicated in eGFR < 30 mL/min. eGFR 31-44 mL/min – Use not recommended. If eGFR < 45 mL/min after initiation - assess benefits and risks of continuing treatment; if eGFR falls < 30 – discontinue	Black Box Warning: Lactic acidosis, rare but potentially serious. Risk increases with degree of renal impairment, CHF or impaired liver function. Discontinue during acute illness or during hunger strikes where dehydration may occur. Adverse events: Nausea, diarrhea, cramping, flatulence May cause vitamin B12 deficiency with anemia and neuropathy which may be confused with diabetic neuropathy Modest weight loss may occur Drug interactions: lodinated contrast agents	Expected A1C reduction: 1.0 - 2.0% Contraindications: Patients with factors predisposing to lactic acidosis: Renal insufficiency with eGFR < 30 mL/min Temporarily discontinue metformin prior to or at time of IV iodinated contrast administration and withhold for 48 hours thereafter. Restart upon confirmation of normal renal function Suspend therapy for surgical procedures and resume with confirmation of normal renal function Pregnancy: Category B Lactation: Enters breast milk, not recommended	
		Sulfonylureas		
Glipizide (Glucotrol [®]) Tablet (IR): 5 mg, 10 mg	Initial dose: 5 mg once daily; 2.5 mg once daily in elderly Titration: Increase dose by 2.5 mg or 5 mg every 1-2 weeks Max dose: 40 mg/day (Doses >15 mg/day should be divided into 2 doses) Hepatic impairment: Initial dose 2.5 mg/day DO NOT USE GLYBURIDE	Adverse events: Hypoglycemia, weight gain, dizziness, nausea, asthenia Increased risk of hypoglycemia when sulfonylurea used with nonbasal insulin Stop when on basal with prandial insulin regimens	Expected A1C reduction: 1.0 - 2.0% Glyburide is no longer recommended due to hypoglycemic risk Best given before a meal, preferably breakfast (if once daily dosing) Possible cross reaction in those allergic to sulfonamides Pregnancy: Category C Lactation: Unknown effect, not recommended	
	THIA	ZOLIDINE-DIONES (TZDS)		
Pioglitazone (Actos [®]) Tablet: 15 mg, 30 mg, 45 mg	Initial dose: 15-30 mg once daily Titration: Increase dose by 15 mg increments Max dose: 45 mg/day Concomitant CYP2C8 inhibitors (e.g., gemfibrozil) or CHF (NYHA class I or II): Max 15 mg/day Hepatic impairment: Moderate or severe: Avoid	Black Box Warning: May cause or exacerbate heart failure. Closely monitor for signs and symptoms of heart failure, especially after initiation or dose increase. If heart failure occurs treat accordingly and consider dose reduction or discontinuation. Adverse effects: Weight gain, edema, CHF, possible hepatic injury; possible increased risk Drug interactions: Strong CYP2C8 inhibitors (e.g., gemfibrozil); CYP2C8 inducers (e.g., rifampin)	Expected A1C reduction: 0.5 - 1.4% Contraindications: Symptomatic CHF; CHF NYHA Class III or IV Caution: Combination use with insulin in patients with heart failure, and CHF NYHA Class I and II Monitor LFTs, avoid if ALT > 2.5 times normal before starting therapy, discontinue if ALT > 3 times normal during therapy If used with insulin, reduce insulin dose by 10-25% once FBG <120 mg/dI Reduce dose of sulfonylurea when used with TZDs to minimize hypoglycemia risk Pregnancy: Category C Lactation: Unknown effect, not recommended medication administration (institution workload, effect on	

adherence) should be considered when determining overall cost-effectiveness of treatment.

Maximum dosage, 25 m/day Renal Impairment: eGFR ≥ 45 mL/min: No dosage adjustment needed eGFR < 45 mL/min: Do not initiate empagliflozin in these patients. In patients currently taking the drug, empagliflozin in these patients. In patients currently taking the drug, empagliflozin in should discontinued when eGFR is persistently < 45 mL/min: 7.73 m² size tent to the shockers, ambidipine, thiazides Patients	SUMMARY	DECISION SUPPORT	PATIENT EDUCATION/SE	LF MANAGEMENT			
SOBJUM-GLUCOSE CO-TRANSPORTER 2 (SLGT2) INHIBITORS SOBJUM-GLUCOSE CO-TRANSPORTER 2 (SLGT2) INHIBITORS Initial dose; 10 mg PO once daily, taken in the morning, with or without food Titration: The dose can be considered to consider the consideration of th	ORAL DM MEDIC	ORAL DM MEDICATIONS CONTINUED					
Initial class: 10 mg PO once daily, taken in the morning, with or without food Turation. The dose can be increased to 25 mg PO once daily oral tablets Initiation: The dose can be increased to 25 mg PO once daily oral tablets Initiation: The dose can be increased to 25 mg PO once daily oral tablets Initiation: The dose can be increased to 25 mg PO once daily oral tablets Population or those who require additional glycemic control Maximum dosage: 25 mg/day Renal Impairment: eGFR ≥ 45 mL/min: No dosage adjustment needed eGFR < 45 mL/min: Do not initiate empagliflozin in these patients. In patients currently taking the drug, empagliflozin should be discontinued when eGFR persistently < 45 mL/min: About the empagliflozin should be discontinued when eGFR persistently < 45 mL/min: About the empagliflozin should be discontinued when eGFR persistently < 45 mL/min: About the empagliflozin should be discontinued when eGFR persistently < 45 mL/min/1.73 m² is DIPEPTIDYL PEPTIDASE-4 (DPP-4) Inhibitors Inhibitors Expected A1C reduction: 0.5 * 0.8%	MEDICATION	Dosing		COMMENTS			
Taken in the morning, with or without or tited			D-TRANSPORTER 2 (SLGT2) IN	IHIBITORS			
Sitagliptin (Januvia®) Tablets: 25 50mg, 100 mg Sitagliptin (Januvia®)	(Jardiance®) 10 mg and 25 mg oral tablets \$\$\$\$\$\$	taken in the morning, with or without food Titration: The dose can be increased to 25 mg PO once daily in those who require additional glycemic control Maximum dosage: 25 mg/day Renal Impairment: eGFR ≥ 45 mL/min: No dosage adjustment needed eGFR < 45 mL/min: Do not initiate empagliflozin in these patients. In patients currently taking the drug, empagliflozin should be discontinued when eGFR is	volume contraction. Symptomatic hypotension can occur after initiating empagliflozin • Dehydration, hypotension, urinary frequency, urinary tract infections, including urosepsis and pyelophritis, balanitis, vaginitis, endocrinopathies, hypoglycemia, hypercholesterolemia, polydypsia • Patients with pre-existing hypercholesterolemia. Monitor LDL-C. Dose-related increases in LDL • Geriatric patients ≥ 75 years old experienced an ↑ incidence of S/E • Drug interactions: Major: chloroquines; Moderate: beta blockers, amlodipine, thiazides, ACEI and ARBs, estrogens, progestins and androgens, HIV "avir" medications, atypical antipsychotics, calcium channel blockers, lithium,	Contraindications: Patients with history of serious hypersensitivity reaction to empagliflozin. Patients with severe renal impairment (eGFR less than 30 mL/min), ESRD/dialysis Cautions: Serious hypersensitivity reactions or anaphylaxis, including angioedema, have been reported in patients receiving empagliflozin Patients at risk of acute kidney injury, include those with dehydration or hypovolemia, particularly in patients with impaired renal function (i.e., eGFR 45 to 60 mL/min), the elderly, patients receiving diuretics, or patients with low systolic blood pressure. Use cautiously in patients with a history of genital fungal infection, including vaginitis or balanitis, and in uncircumcised males Pregnancy: Category C			
Sitagliptin (Januvia®) Tablets: 25 50mg, 100 mg Nonformulary preferred 100 mg once daily Max dose: 100 mg/day Renal impairment: CrCl 30-49 ml/min: 50 mg daily CrCl < 30 ml/min: 25 mg daily Nonformulary preferred 100 mg once daily Max dose: 100 mg/day Renal impairment: CrCl 30-49 ml/min: 50 mg daily CrCl < 30 ml/min: 25 mg daily Assess renal function prior to initiation and periodically thereafter Reduce dose of sulfonylurea or insulin when used with sitagliptin to minimize hypoglycemia risk Pregnancy: Category B Lactation: Unknown effect, use caution INJECTABLE MEDICATIONS - (INJECTABLE INSULIN MEDICATIONS)			EPTIDASE-4 (DPP-4) INHIBITOI	RS			
	(Januvia [®]) Tablets: 25 mg, 50mg, 100 mg	100 mg once daily Max dose: 100 mg/day Renal impairment: CrCl 30-49 ml/min: 50 mg daily	diarrhea, nausea, abdominal pain Rare severe hypersensitivity reactions including anaphylaxis, angioedema, exfoliative dermatitis, especially within first three months of therapy Acute pancreatitis Severe and disabling arthralgias Drug interactions: Major: CYP3A4/5	 Assess renal function prior to initiation and periodically thereafter Reduce dose of sulfonylurea or insulin when used with sitagliptin to minimize hypoglycemia risk Pregnancy: Category B 			
	INJECTABLE MED		INSULIN MEDICATIONS)				

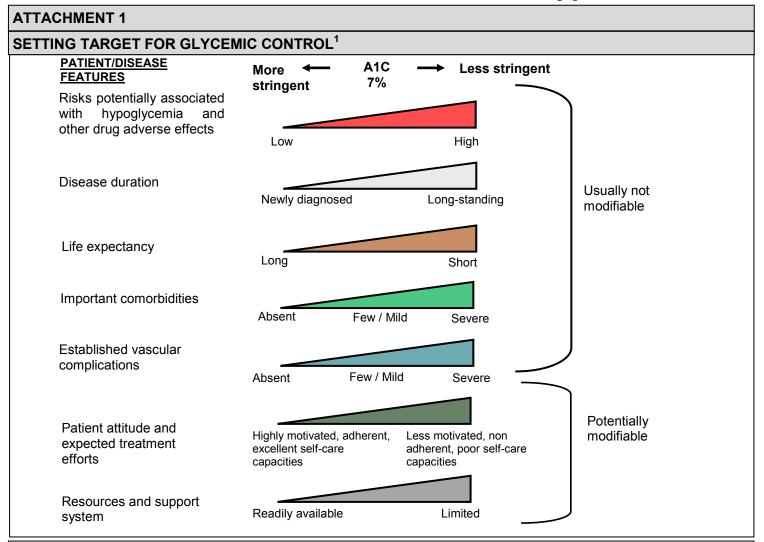
INJECTABLE MEDICATIONS - (INJECTABLE INSULIN MEDICATIONS)						
INSULIN CLASS Please see treatment algorithm on page 3	SPECIFIC INSULIN	ONSET	PEAK	DURATION	Соѕт	
Short-acting*	egular– Humulin R [®]	30-60 minutes	2 to 4 hours	5 to 10 hours	\$\$	
Intermediate-acting NF	PH—Humulin N [®]	1 to 2 hours	4 to 8 hours	10 to 20 hours	\$\$	
Premixed NF	PH/regular—Humulin 70/30 [®]	30 minutes	Dual peak	Up to 24 hours	\$\$	
	largine—Lantus [®] lot to be mixed with other insulins)	1 to 2 hours	Relatively flat	20 to 24 hours	\$\$\$\$	
IN CORRECTIONAL SETTING AS	spro (Humalog) spart (Novolog) lulisine (Apidra)	15-30 minutes 10-20 min 20-30 min	30-90 min 40-50 min 30-90 min	3-5 hours 3-5 hours 1 to 1.5 hours	\$\$\$\$	

^{*}Every effort should be made to administer rapid-acting insulin before meals. However in rare circumstances when patient movement may be disrupted and risk of hypoglycemia is high, rapid acting insulin may be administered shortly after meals.

The cost scale \$-\$\$\$\$ represents the relative cost of acquisition of medication only. Frequency and complexity of medication administration (institution workload, effect on adherence) should be considered when determining overall cost-effectiveness of treatment.

SUMMARY	DECISION SUPPORT	PATIENT EDUCATION/S	SELF MANAGEMENT		
INJECTABLE	INJECTABLE HYPOGLYCEMIC MEDICATIONS - NONINSULINS				
MEDICATION	Dosing	ADVERSE EFFECTS / INTERACTIONS*	COMMENTS		
	GLUCAGON-LIKE PEPTIL	DE-1 (GLP-1) AGONIST (INCR	ETIN MIMETIC)		
Liraglutide (Victoza®) Injection soln: 1 mL, 6 mg \$\$\$\$\$ Nonformulary preferred	Initial dose: Administer once daily at any time of day, independently of meals. Initially, 0.6 mg subcutaneously once daily for 1 week. The 0.6 mg dose is a starting dose intended to reduce gastrointestinal (GI) symptoms during initial titration and is not effective for glycemic control. Administer by subcutaneous injection only. Do not administer by intravenous or intramuscular injection. Titration: After 1 week, increase the dose to 1.2 mg subcutaneously once daily. If acceptable glycemic control not achieved, the dose can be increased to 1.8 mg subcutaneously once daily. If a dose is missed, resume the once daily regimen as prescribed with the next scheduled dose. If more than 3 days have elapsed since the last dose, reinitiate at 0.6 mg in order to alleviate any GI symptoms associated with re-initiation of treatment. The dose should then be re-titrated appropriately. Max dose: 1.8 mg/day SC	 Black Box Warning: Liraglutide has been shown to cause dose-dependent and treatment duration-dependent malignant thyroid C-cell tumors at clinically relevant exposures in animal studies at 8 times normal dose. Relevance in humans is not known. Adverse effects: GI: Slows gastric emptying with resultant nausea, vomiting and diarrhea. Anorexia, dyspepsia, headache, flatulence, constipation, hypoglycemia Hypoglycemia should be monitored by the patient and clinician when liraglutide treatment is initiated and continued Fatigue, infections, dizziness, antibody formation, injection site reactions Severe but less common: Cholecystitis, pancreatitis, AV Block, suicidal ideation, angioedema, anaphylactoid reactions, bronchospasm, palpitations Drug Interactions: Major: hydroxyquinalone and chloroquine Moderate: Salicylates, Beta Blockers Acetaminophen, ASA, caffeine, Phenyltoloxamine, lithium Acetazolamide, Aliskiren Valsartan, Amlodipine, HCTZ, Androgens, progestins and estrogens, Metoclopramide, ACE I and ARBs, omeprazole, oxycodone, fibric acid derivatives, fluoxetine, Insulins, Sulfanamides, Calcium channel blockers, Dirunavir, cyclosporins, Clonidine, Ciprofloxin Hypoglycemia was increased when liraglutide was used in combination with a sulfonylurea or discontinuing when starting liraglutide. Liraglutide has not been evaluated for use in combination with prandial insulin. 	 Expected A1C reduction: 0.5-1.0% Contraindications: Patients with a personal or family history of certain types of thyroid carcinoma (MTC), or in patients with multiple endocrine neoplasia syndrome type 2 (MEN 2). Patients with a history of serious hypersensitivity reaction to liraglutide Caution: Patients with a history of angioedema to other GLP-1 receptor agonists. Serious hypersensitivity reactions have been reported during post marketing use with liraglutide, such as anaphylaxis or angioedema Liraglutide should not be used in patients with Type 1 DM or for the treatment of diabetic ketoacidosis Use caution in patients with gastroparesis. There is limited information available on the use of liraglutide in patients with renal impairment There is limited information available on the use of liraglutide in patients with hepatic disease Patients with risk factors for pancreatitis (cholelithiasis, GB disease, alcoholism, prior history) Pregnancy: Category C Lactation: Unknown effect, use caution Caution: Patients with depression and avoid use in patients with a history of suicide attempts or active suicidal ideation. Monitor patients receiving liraglutide for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior. 		

The cost scale \$-\$\$\$\$ represents the relative cost of acquisition of medication only. Frequency and complexity of medication administration (institution workload, effect on adherence) should be considered when determining overall cost-effectiveness of treatment.



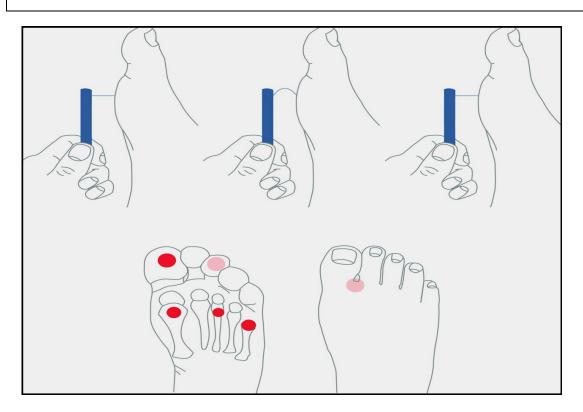
- This "scale" is not designed to be applied rigidly but to be used as a broad construct to help guide clinical decisions.
- Those with long duration of diabetes, known history of severe hypoglycemia, advanced atherosclerosis, and advanced age/frailty may benefit from less aggressive targets.
- Providers should be vigilant in preventing severe hypoglycemia in patients with advanced disease and should not
 aggressively attempt to achieve near-normal A1C levels in patients in whom such targets cannot be safely and reasonably
 achieved.

¹Adapted from: Management of Hyperglycemia in Type 2 Diabetes, 2015: A Patient-Centered Approach: Update to a Position Statement of the American Diabetes Association and the European Association for the Study of Diabetes. Silvio E. Inzucchi, Richard, M. Bergenstal, John B. Buse, Michaela Diamant, Ele Ferrannini, Michael Nauck, Anne L. Peters, Apostolos Tsapas, Richard Wender, David R. Matthews. Diabetes Care Jan 2015, 38 (1) 140-149; DOI: 10.2337/dc14-2441.

ATTACHMENT 2

MONOFILAMENT TESTING¹ (SINGLE USE DISPOSABLE MONOFILAMENTS ARE RECOMMENDED)

- 1. Place patient in supine or sitting position with shoe and socks removed.
- 2. Touch the disposable monofilament to patient's skin on his/her arm or hand to demonstrate what the touch feels like.
- 3. Instruct patient to respond "yes" each time he/she feels the pressure of the monofilament on his/her foot during the exam.
- 4. Instruct patient to close his/her eyes with toes pointing straight up during the exam.
- 5. Hold the monofilament perpendicular to the patient's foot (see top panel of diagram below).
- 6. Press it against the foot, increasing the pressure until the monofilament bends into a C-shape. Do not apply over ulcer, callus, scar, or necrotic tissue. Do not slide monofilament over the skin.
- 7. Inform the patient you will test each location twice, one touch will be real and one will not. Press the filament to the skin such that it buckles (and hold in place for about 1 second) at one of two times you test each site as you say "time one" or "time two." Have patients identify at which time they were touched.
- 8. It is recommended to test at least 4 sites on each foot (see lower panel of diagram below: 1st, 3rd, and 5th metatarsal heads and plantar surface of distal hallux, other spots are optional).
- 9. Randomize the sequence of applying the filament or not throughout the examination.
- 10. Record response on foot screening form with "+" for yes it was felt and "-" for no. The patient should recognize the perception of pressure and identify the correct site.
- 11. When the monofilament is not felt, protective sensation is absent, placing the person at high risk for development of a neuropathic ulcer.



Record a "+" if the patient can feel the monofilament

Record a "-" if the patient is unable to feel the monofilament

¹Boulton AJM, Armstrong DG, Albert SF, et al. Comprehensive Foot Examination and Risk Assessment: A report of the Task Force of the Foot Care Interest Group of the American Diabetes Association, with endorsement by the American Association of Clinical Endocrinologists . *Diabetes Care*. 2008;31(8):1679-1685. doi:10.2337/dc08-9021.

ATTACHMENT 3

DETECTION AND DIAGNOSIS OF GESTATIONAL DIABETES MELLITUS (GDM)¹

Patients should be screened in the first trimester who have a BMI ≥ 25 kg/m2 and any of the following risk factors:

- Physical inactivity
- First degree relative with DM
- High-risk race/ethnicity (African American, Latino, Native American, Asian American, Pacific Islander)
- Hypertension (BP > 140/90 mmHg or on treatment for Hypertension)
- Hypercholesterolemia
- A1C ≥ 5.5% (36.6 mmol/mol, IGT, IFG on previous testing)
- Delivered a baby weighing > 9 pounds (4.1 kg) or previously diagnosed with GDM
- Clinical conditions associated with insulin resistance (e.g., Acanthosis nigricans, Polycystic Ovarian Syndrome)
- · History of CVD
- Smoking

All pregnant patients who were not screened in the first trimester, should be tested for GDM at 24-28 weeks of gestation. [A]

Screening and Diagnosis:

1. Perform an 8 hour fasting 75-g OGTT at 24-28 weeks of gestation in women not previously diagnosed with overt DM.

Diagnostic for GDM if:

- Fasting: 92 mg/dl (a fasting glucose of > 126 is diagnostic of overt DM [Pre-gestational diabetes])
- ♦ 1 h: 180 mg/dl
- ♦ 2 h: 153 mg/dl
- 2. Two-Step non-fasting 50 g Glucose Load Testing
 - ↑ 1 h: if it is ≥ 140 mg/dl, proceed to a fasting 100-g OGTT
 - Diagnostic for GDM if (at least two of the following four):

Fasting 1 hour	95 mg/dl 180 mg/dl		105 mg/dl 190 mg/dl
2 hour	155 mg/dl		165 mg/dl
3 hour	140 mg/dl		145 mg/dl
Carpente	er/Coustan* or	NDDG**	

Thresholds vary depending on the organization/authors. The most commonly cited (per Up to Date) are listed here:

DIAGNOSED WITH GDM- WHAT TO DO

REFER to OBSTETRICS. These patients should be followed as <u>high-risk</u> pregnancies.

CHECK MEDICATIONS (e.g., ACEIs, statins are teratogenic.) Discharge medications not compatible with pregnancy.

REFER TO DIETITIAN.

REFER TO OPHTHALMOLOGY/OPTOMETRY—GDM high risk for retinopathy or progression.

- 1) Retinal eye exams should occur before pregnancy or in the 1st trimester
- 2) Monitor every trimester and for up to 1 year post-partum as indicated by the degree of retinopathy and recommendations of eye care provider. **[B]**

USE INSULIN for hyperglycemia not controlled with lifestyle. Glycemic control as close to normal as is safely possible, ideally A1C < 6.5%, to reduce the risk of congenital anomalies.* **[B]**

*Uncontrolled glycemia during gestation is associated with miscarriage, stillbirth, preterm labor and delivery, large birthweight and C-Sec, postnatal hypoglycemia, ancephaly, microcephaly, spinal cord lesions, congenital heart disease, generic anomalies, and cleft palate.

^{*}Carpenter MW, Coustan DR. Criteria for screening tests for gestational diabetes. Am J Obstet Gynecol 1982;144:768–773.

^{**}NDDG: National Diabetes Data Group. Classification and diagnosis of diabetes mellitus and other categories of glucose intolerance. Diabetes 1979;28:1039–1057.

ATTACHMENT 4	
	ADA EVIDENCE- GRADING SYSTEM ¹
Level of Evidence	Description
[A]	Clear evidence from well-conducted, generalizable randomized controlled trials that are adequately powered, including: • Evidence from a well-conducted multicenter trial • Evidence from a meta-analysis that incorporated quality ratings in the analysis Compelling nonexperimental evidence, i.e., "all or none" rule developed by the Centre for Evidence-Based Medicine at the University of Oxford Supportive Evidence from well-conducted randomized controlled trials that are adequately powered, including: • Evidence from a well-conducted trial at one or more institutions • Evidence from a meta-analysis that incorporated quality ratings in the analysis
[B]	Supportive evidence from well-conducted cohort studies • Evidence from a well-conducted prospective cohort study or registry • Evidence from a well-conducted meta-analysis of cohort studies Supportive evidence from a well-conducted case control study
[C]	 Supportive evidence from poorly controlled or uncontrolled studies Evidence from randomized clinical trials with one or more major or three or more minor methodological flaws that could invalidate the results Evidence from observational studies with high potential for bias (such as case series with comparison with historical controls) Evidence from case series or case reports Conflicting evidence with the weight of evidence supporting the recommendation
[E]	Expert consensus or clinical experience

The ADA classification system for grading evidence is used to clarify and codify the evidence that forms the basis for the current recommendations. The ratings of **[A]**, **[B]**, or **[C]** are based on the quality of evidence with **[A]** recommendations having "the best chance of improving outcomes when applied to the population to which they are appropriate." An **[E]** recommendation is a separate category and relies on expert consensus or clinical experience.².

¹Adapted from ADA 2018, Diabetes Care Volume 41, Supplement 1, Table 1, January 2018.

²American Diabetes Association. "Introduction: Standards of Medical Care in Diabetes--2018." *Diabetes Care* (2018): S1-S2.

PATIENT EDUCATION/SELF MANAGEMENT

DIABETES: WHAT YOU SHOULD KNOW

WHAT IS DIABETES?

Diabetes is a disease that causes high amounts of glucose (sugar) in the blood. It is caused by the body not making enough insulin or not being able to use the insulin it has.

Diabetes can lead to serious health problems including:

- High blood pressure
- Eye/vision problems
- Kidney disease
- Digestive problems
- Amputation of toes or feet
- Heart attacks
- Strokes
- Nerve damage throughout your body
- Skin problems



SYMPTOMS TO WATCH FOR IF YOU HAVE DIABETES

High blood sugar (hyperglycemia) symptoms

- Thirst
- Frequent urination
- Blurred vision



Low blood sugar (hypoglycemia) symptoms

- Shaky
- Sweating
- Fast Heart beat
- Nausea
- Drowsiness
- Coma

- Hungry
- Headache Confusion
- Cranky
- Tired
 - Seizures

What are the causes of high blood sugar?

- Too much food
- Too little diabetes medicine
- Illness
- Stress

HEADACHY

- Too little food
- Extra exercise
- Too much diabetes medicine or insulin

What to do if you have symptoms of high blood sugar

- Be sure to drink plenty of water
- Contact your health care team

What to do if you have symptoms of low blood sugar

- Immediately tell someone what is going on.
- If your symptoms are mild you can try to eat or drink something.
- Eat or drink something with sugar in it.
- Contact your health care team if you don't feel better in 15 minutes.



PATIENT EDUCATION/SELF MANAGEMENT

DIABETES: WHAT YOU SHOULD DO

KNOW THE ABCS OF DIABETES:

A

A₁C

- The A1C is a blood test that measures your blood sugar level over the past three months.
- It is different from the blood sugar checks you do from your finger.
- A1C is usually less than 6.5% in people without diabetes. In people with diabetes the goal is an A1C less than 7-8% (your health care provider will tell you what your personal A1C goal should be as the goal is different for different people).



B

Blood pressure

- Blood pressure is the force of your blood against the walls of your blood vessels.
- If your blood pressure gets too high, it makes your heart work too hard.
- High blood pressure can cause a heart attack, kidney disease, or a stroke.
- Your blood pressure should be below 140/90 unless your health care provider tells you a different goal.
- Blood pressure control is important in diabetes. Be sure to have your blood pressure checked at every health care visit.





Cholesterol (ko-LESS-tuh-ruhl)

- Cholesterol is a chemical in your blood. LDL is the "bad" cholesterol that can build up and clog your blood vessels, which can cause a heart attack or stroke.
- Most people with diabetes are prescribed medication called "statins" to lower their "bad" cholesterol.
- Your health care provider will check your blood LDL cholesterol level, often once a year, but sometimes less often if you are taking statin medication.

WHAT ELSE SHOULD YOU DO IF YOU HAVE DIABETES?

- · Do not smoke.
- Take your medications as directed.
- Control your weight. The best way to maintain a good weight is to eat a healthy diet and exercise more.
 - ▶ Be active at least 30 minutes on most days. You can walk, jog, or do exercises in your cell, even during lockdowns.
 - ► Eat a healthy diet: limit breads and pastas, canteen-junk foods, candy, and ice cream.
- Try to lower stress levels.
- Check your feet every day for cuts, blisters, red spots, and swelling.
- Report any changes in your vision to your health care provider.
- Be sure to get regular check-ups.
- Talk to health care staff about when you should get lab tests including A1C, and when you should get foot, eye, dental, and EKG exams to monitor your condition.

BENEFITS OF EXERCISE IF YOU HAVE DIABETES

- Weight loss and maintenance of normal weight.
- A stronger, healthier heart.
- Improved sleep.
- Improved mood.
- Improved blood pressure, cholesterol, and blood glucose levels.
- May help lower the amount of medication needed to control your blood sugar.



PATIENT EDUCATION/SELF MANAGEMENT

DIABETES: FOOT CARE

WHY IS FOOT CARE IMPORTANT?

Diabetes can cause you to lose feeling in your feet (feet are numb).

When you have numbness or can't feel your feet, they can get injured, often without you knowing it, from:

- Something that breaks your skin (such as a cut)
- A deep wound (such as stepping on something sharp)
- · Walking barefoot on a hot surface
- Constant pressure in one spot (from a tight shoe)

HOW DO I KEEP MY FEET HEALTHY?

- Check your feet every day.
 - Look for red spots, sores, infected toenails, swelling, cuts, and blisters.
- Wear shoes and socks at all times.
- Wear comfortable shoes that protect your feet and fit well.
- Protect your feet from hot and cold.
- Keep blood flowing to your feet.
 - Put your feet up when sitting.
 - Move your ankles and wiggle your toes throughout the day.
 - Do not cross your legs for long periods of time.
- Wash your feet every day.
 - Dry your feet carefully, especially between the toes.
- Keep the skin of your feet soft and smooth.
 - If you have lotion you can use a thin coat over the tops and bottoms of your feet, but not between your toes.
- Carefully trim your toenails regularly. Ask your health care team for assistance if needed.
- Take care of your diabetes.
 - Work with your health care provider to keep your blood levels in your target range.
- Don't smoke.





HOW DO I TREAT FOOT PROBLEMS?

Talk to your health care provider if you have any foot problems.









EDUCACIÓN PARA EL PACIENTE/CONTROL PERSONAL DEL CASO

DIABETES: LO QUE DEBE SABER

¿QUÉ ES LA DIABETES?

La diabetes es una enfermedad que genera altas cantidades de glucosa (azúcar) en la sangre. Es causada cuando el organismo no produce suficiente insulina o no es capaz de usar la que tiene.

La diabetes puede llevar a problemas severos de salud como:

- Presión arterial alta
- Problemas en ojos/visión
- Enfermedades renales
- Problemas digestivos
- · Amputación del pie o de sus dedos
- Ataques cardíacos
- Derrames cerebrales
- Daños a los nervios en todo el cuerpo



SÍNTOMAS QUE DEBE CONTROLAR SI TIENE DIABETES

Síntomas de altos niveles de azúcar en la sangre (hiperglicemia)

- Sed
- Micción frecuente
- Visión borrosa

Síntomas de bajos niveles de azúcar en la sangre (hipoglicemia)

- Tembloroso
- Transpiración
- Latidos cardíacos acelerados
- Náuseas
- Somnolencia
- Coma

- Hambre
- Dolor de cabeza
- Confusión
- De maniático
- Cansado
- Convulsiones



¿Cuáles son las causas de los altos niveles de azúcar en la sangre?

- Demasiada comida
- Poco medicamento para la diabetes
- Enfermedad
- Estrés

¿Cuáles son las causas de los altos niveles de azúcar en la sangre?

- Muy poca comida
- Ejercicio extra
- Demasiado medicamento para la diabetes o insulina

Lo que debe hacer cuando hay síntomas de altos niveles de azúcar en la sangre

- Asegúrese de tomar mucha agua
- Comuniquese con su elenco tratante

Lo que debe hacer cuando hay síntomas de bajos niveles de azúcar en la sangre

- Immediamente dile a alguien lo que está pasando.
- Si sus síntomas son leves, puede intentar comer o beber algo.
- Coma o beba algo que contenga azúcar.
- Comuníquese con su elenco tratante si no se siente mejor en los siguientes 15 minutos.

EDUCACIÓN PARA EL PACIENTE/CONTROL PERSONAL DEL CASO

DIABETES: LO QUE DEBE HACER

CONOZCA LOS PUNTOS IMPORTANTES DE LA DIABETES:

A₁C

- La A1C es una prueba sanguínea que mide su nivel de azúcar en la sangre en los tres meses anteriores.
- Es diferente de las pruebas de azúcar en la sangre de su dedo.
- La A1C es, normalmente, inferior a 6.5% en las personas sin diabetes. En las personas con diabetes, la meta es un A1C inferior al 7-8% (su elenco tratante le dirá cual debería ser su meta A1C personal, ya que esta meta es diferente para cada persona).



2

Presión arterial

- La presión arterial es la fuerza de su sangre contra las paredes de sus vasos sanguíneos.
- Si su presión arterial se eleva mucho, hace trabajar demasiado a su corazón.
- La presión arterial alta puede causar un ataque cardíaco, enfermedad renal o un derrame cerebral.
- Su presión arterial debería ser menor de 140/90 a menos que su médico le indique otra meta a alcanzar.
- El control de la presión arterial es importante en la diabetes. Asegúrese de hacerse revisar su presión arterial en cada consulta médica.



3

Colesterol

- El colesterol es una sustancia química en su sangre. LDL es el colesterol "malo" que puede acumularse y obstruir sus vasos sanguíneos, lo que puede causar un ataque cardíaco o un derrame cerebral.
- A la mayoría de las personas con diabetes se les prescribe medicamentos llamados "estatinas" para reducir su colesterol "malo."
- Su médico controlará su nivel de colesterol LDL en la sangre, frecuentemente una vez al año, pero a veces con menos frecuencia si está tomando estatinas.

¿QUÉ MÁS DEBERÍA HACER SI TIENE DIABETES?

- No fume.
- Tome sus medicamentos tal como le sean prescritos.
- Controle su peso. La mejor manera de mantener un buen peso es llevar una dieta sana y ejercitarse más.
 - ► Haga alguna actividad al menos 30 minutos la mayoría de los días. Puede caminar, trotar o hacer ejercicio en su celda, aún durante un encierro institucional.
 - ► Lleve una dieta sana: limite los panes y pastas, las comidas chatarra compradas en la cantina, golosinas y helados.
- Intente reducir sus niveles de estrés.
- Revise sus pies diariamente; busque cortadas, ampollas, puntos rojos e inflamación.
- Informe a su médico cualquier cambio en su visión.
- Asegúrese de tener chequeos médicos regulares.
- Hable con el personal médico para saber cuándo debe hacerse pruebas de laboratorio, incluyendo la A1C, y cuándo debe recibir exámenes de los pies, los ojos, los dientes, y un electrocardiograma para controlar su condición.

BENEFICIOS DEL EJERCICIO SI TIENE DIABETES

- Pérdida de peso y mantenimiento de un peso normal.
- Un corazón más fuerte y sano.
- Un sueño mejorado.
- Un estado de ánimo mejorado.
- Una presión arterial mejorada, además de niveles de colesterol y glucosa en la sangre mejorados.
- Podría ayudar a reducir la cantidad de medicamentos necesarios para controlar el azúcar en la sangre.





EDUCACIÓN PARA EL PACIENTE/CONTROL PERSONAL DEL CASO

DIABETES: CUIDADO DE LOS PIES

¿POR QUÉ ES IMPORTANTE EL CUIDADO DE LOS PIES?

La diabetes puede hacer que pierda sensación en sus pies (los pies se entumecen).

Cuando tiene entumecimiento o no puede sentir sus pies, estos se pueden herir y frecuentemente sin que usted se dé cuenta, por:

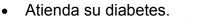
- Algo que le rompa la piel (como una cortada)
- Una herida profunda (como cuando pisa algo puntiagudo)
- Caminar descalzo sobre una superficie caliente
- Presión constante en algún punto determinado (por un calzado apretado)

¿CÓMO MANTENGO MIS PIES SANOS?

- Revise sus pies diariamente.
 - Busque puntos rojos, llagas, uñas infectadas, inflamación, cortadas y ampollas.



- Siempre use zapatos y calcetines.
- Use zapatos cómodos que protejan sus pies y calcen bien.
- Proteja sus pies del calor y del frío.
- Mantenga la sangre circulando a sus pies.
 - Levante los pies mientras esté sentado.
 - Mueva sus tobillos y los dedos de los pies durante el curso del día.
 - No mantenga sus piernas cruzadas durante largos periodos de tiempo.
- Lave sus pies todos los días.
 - Seque sus pies con cuidado, especialmente entre los dedos.
- Mantenga la piel de sus pies suave y terso.
 - Si tiene loción puede usar una capa delgada sobre las partes superiores e inferiores de sus pies, pero no entre los dedos.
- Con cuidado, córtese las uñas de los dedos de los pies regularmente.
 Pida ayuda a su elenco tratante de ser necesario.



- Trabaje con su médico para mantener sus niveles de azúcar en la sangre dentro del rango establecido como meta.
- No fume.
- Realice más actividades.





¿CÓMO TRATO LOS PROBLEMAS DE LOS PIES?

Hable con su médico si tiene algún problema con los pies.



